

CASE AUTH/3375/8/20

VOLUNTARY ADMISSION BY DAIICHI-SANKYO

Breach of undertaking

Daiichi-Sankyo UK Ltd voluntarily admitted that it had breached its undertaking in Case AUTH/3285/12/19 in that further transfers of value had not been included in the company's submissions to Disclosure UK. The transfers of value related to a therapy review service provided via a third-party to general practices. The relevant data had been collated but not submitted. The matter had come to light as Daiichi-Sankyo prepared for the audit required by the Appeal Board in Case AUTH/3285/12/19.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Daiichi-Sankyo.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted that in Case AUTH/3285/12/19 Daiichi-Sankyo had been ruled in breach of the Code for under-reporting transfers of value in relation to support given to health professionals to attend conferences in 2016, 2017 and 2018 and for failing to have adequate processes in place to correctly disclose such transfers of value; the Panel in that case had been extremely concerned as to the scale of under-reporting and Daiichi-Sankyo's inadequate processes in that regard and further breaches of the Code were ruled.

Turning to the current case, the Panel noted Daiichi-Sankyo's submission that transfers of value of around £800 000 to healthcare organisations in 2017, 2018 and 2019 in relation to therapy reviews were missing from its Disclosure UK submissions in 2018, 2019 and 2020, respectively.

The Panel considered that the information published on Disclosure UK when the voluntary admission was submitted in August 2020 was not comprehensive in relation to 2017 and 2018 transfers of value provided to healthcare organisations for therapy reviews; Daiichi-Sankyo had not met the requirement to disclose by 30 June of the relevant year. The Panel ruled breaches of the Code for each of those years.

The Panel noted that during the Covid-19 pandemic in 2020, the ABPI and the PMCPA agreed that it would not be appropriate to write to NHS workers, hospitals or other NHS organisations while they were otherwise focussed on responding to the pandemic. To prevent the annual communications from being distributed, on 30 June 2020 companies' 2019 non-R&D data was temporarily published on Disclosure UK in aggregate, instead of being broken down by individuals and organisations. The Panel noted that companies were, however, encouraged to publish the detailed 2019 data on their own websites where possible. The 2019 disclosure data was re-published on 27 November 2020 disaggregated, as normal on Disclosure UK.

The Panel noted that the temporary change to disclosure as a result of the pandemic should not have affected Daiichi-Sankyo's disclosure of its 2019 transfers of value to healthcare organisations in relation to therapy reviews in aggregate by 30 June 2020. The Panel noted, however, that Daiichi-Sankyo had not submitted the relevant data to Disclosure UK. The Panel therefore considered that the information published on Disclosure UK when the voluntary admission was submitted in August 2020 was not comprehensive in relation to 2019 transfers of value provided to healthcare organisations for therapy reviews. Consequently, as the data had not been disclosed, Daiichi-Sankyo had not met the requirement to disclose the data, albeit in aggregate in the temporary circumstances described above, by 30 June 2020. Breaches of the Code were ruled.

The Panel was concerned to note Daiichi-Sankyo's submission that whilst it had reconciled and collated the healthcare organisation-level details for the therapy review invoices in its system for £822,000 (96%) of the total amount, which included £65,000 in 2017, £259,000 in 2018 and £498,000 in 2019, there was still £35,000 (4%) that could not be fully identified as a service provider no longer had records for 2017. The Panel thus queried whether the company's original submission that it had collated the data to begin with was thus completely accurate.

The Panel considered that the magnitude of under-reporting was of serious concern and queried why the issue had not come to light sooner particularly given that the company's undertaking in Case AUTH/3285/12/19 was provided on 13 February 2020. The error had only been identified as a result of an audit that Daiichi-Sankyo had commissioned to assess the robustness of its Code-related governance framework. Daiichi-Sankyo had submitted that the root cause explanation for the reporting oversight was that its processes failed to identify that the therapy reviews were within the scope of disclosure.

The Panel noted that the disclosure of transfers of value was an important part of self-regulation and it was of serious concern that Daiichi-Sankyo had significantly under-reported transfers of value to healthcare organisations in relation to therapy reviews for so many years. High standards had not been maintained and therefore the Panel ruled a breach of the Code as acknowledged by Daiichi-Sankyo.

The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. It considered that the failure to disclose the required information on Disclosure UK was extremely concerning as was the scale of the under-reporting. Daiichi-Sankyo's processes were wholly inadequate in that regard. The Panel ruled a breach of Clause 2.

The Panel noted that a form of undertaking and assurance was an important document which underpinned self-regulation. Companies had to give an undertaking that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that Daiichi-Sankyo had provided its undertaking in relation to Case AUTH/3285/12/19 on 13 February 2020. In the Panel's view, whilst the failure to disclose the 2017 and 2018 transfers of value to healthcare organisations in relation to therapy reviews by 30 June 2018 and 30 June 2019, respectively, were not covered by that

undertaking, the Panel noted that, when this voluntary admission was submitted in August 2020, the relevant data for 2017 and 2018 had still not been disclosed. Furthermore, the Panel noted that 2019 transfer of values to healthcare organisations in relation to therapy reviews had not been disclosed, albeit in aggregate in the temporary circumstances due to the Covid-19 pandemic, by 30 June 2020. It appeared that the company's processes in relation to disclosing transfers of value as required by the Code remained inadequate. In the Panel's view, Daiichi-Sankyo had breached its undertaking given in Case AUTH/3285/12/19 and a breach of the Code was ruled.

The Panel considered that Daiichi-Sankyo's failure to comply with its undertaking given in Case AUTH/3285/12/19 meant that it had not maintained high standards and had brought discredit upon, and reduced confidence in, the industry. Breaches of the Code, including of Clause 2, were ruled.

The Panel considered that, on balance, and bearing in mind the need for proportionate regulation it would not report Daiichi-Sankyo to the Appeal Board as closely similar matters had been at issue in Case AUTH/3285/12/19 which had led to the ongoing audit process and a forthcoming re-audit would refer to this case.

Daiichi-Sankyo UK Ltd voluntarily admitted that it had breached its undertaking in Case AUTH/3285/12/19: Disclosure of payments on Disclosure UK.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Daiichi-Sankyo.

COMPLAINT

Daiichi-Sankyo noted that the audit required by the Code of Practice Appeal Board in Case AUTH/3285/12/19 was due to take place on 9 September 2020 and that its corrective actions associated with the learning from that case, and its preparations for the audit, had highlighted a further issue related to disclosure.

Daiichi-Sankyo stated that it had provided a therapy review service via a third-party service provider to general practices across the UK. It now appeared that even though Daiichi-Sankyo had collated the data relevant to the transfers of value associated with this benefit-in-kind, the values had not been included in its submission to Disclosure UK.

Daiichi-Sankyo stated that it therefore acknowledged a breach of Clause 29 of the Code and a breach of Clause 24.1 because of the inaccuracy of its disclosures.

Daiichi-Sankyo noted that the Constitution and Procedure required a formal complaint to be raised against the company and as such it would continue its internal investigations and provide the full details as part of the formal response. Daiichi-Sankyo stated that, at this stage, the sums of money were significant at around £500,000 in 2019 and approximately £300,000 in 2018.

Daiichi-Sankyo stated that it took its obligations under the Code seriously and it apologised for the fact this issue had arisen.

When writing to Daiichi-Sankyo, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 24.4 of the Code in addition to Clauses 24.1 and 29 cited by the company.

RESPONSE

Daiichi-Sankyo stated that it provided a therapy review service via several third-party service providers to general practices across the UK. The transfers of value associated with this benefit-in-kind, were not captured in the company's submission to Disclosure UK.

Daiichi-Sankyo's internal investigations had showed that the £857,000 therapy review transactions were missing from its Disclosure UK submission. Daiichi-Sankyo stated that it had worked hard over the past few weeks with the three service providers to reconcile and collate the healthcare organisation-level details for the therapy review invoices in its system. Daiichi-Sankyo stated that it had managed to do this for £822,000 (96%) of the transfer of value amounts, leaving £35,000 (4%) that could not be fully identified as a service provider no longer had records for the calendar year 2017. The £822,000 reconciled totals by calendar year were as follows:

- 2017: healthcare organisations with a combined total disclosure value of £65,000.
- 2018: healthcare organisations with a combined total disclosure value of £259,000.
- 2019: healthcare organisations with a combined total disclosure value of £498,000.

Daiichi-Sankyo submitted that its processes failed to identify that the therapy reviews were within the scope of disclosure of transfers of value. The error came to light after the 2019 transfers of value were submitted to Disclosure UK and was identified as a result of an audit commissioned by Daiichi-Sankyo to assess the robustness of its Code-related governance framework.

Daiichi-Sankyo stated that on identifying the error, it immediately began a detailed analysis of payments made to the therapy review service providers so it could identify amounts paid to the recipient general practices. Daiichi-Sankyo had now reconciled the numbers with all but one of the service providers who had not retained records from its activities in 2017. As noted above, the unreconciled discrepancy for 2017 was £35,000.

Daiichi-Sankyo submitted that since the error was identified, it had changed its procedure for payments to suppliers so that suppliers only received full settlement of invoices after they provided a breakdown of payments they make to health professionals/healthcare organisations etc on behalf of the company. Further, the Disclosure standard operating procedure (SOP) had been changed to explicitly identify therapy reviews as elements for checking and disclosure. Daiichi-Sankyo also submitted that disclosure training would be updated accordingly and updated templates would be created to reconcile contracted payments made by Daiichi-Sankyo and the therapy review providers and the onward benefit-in-kind transferred to recipient healthcare organisations. Finally, therapy reviews would be added to transfers of value monitoring.

Daiichi-Sankyo acknowledged that it had breached Clauses 2, 9.1, 24.1, 24.4 and 29 because of its failure to report therapy review payments on Disclosure UK and apologised for the fact this issue had arisen.

PANEL RULING

The Panel noted that in Case AUTH/3285/12/19 Daiichi-Sankyo had been ruled in breach of the Code for under-reporting transfers of value in relation to support to health professionals to attend conferences in 2016, 2017 and 2018 and for failing to have adequate processes in place to correctly disclose such transfers of value. As the data had not been disclosed, Daiichi-Sankyo had not met the requirement to disclose by 30 June of the relevant year and the Panel ruled breaches of Clauses 24.1 and 24.4. The Panel further ruled a breach of Clause 2 as it was extremely concerned as to the scale of under-reporting and Daiichi-Sankyo's inadequate processes in that regard. Those rulings were accepted by Daiichi-Sankyo and it provided a signed undertaking on 13 February 2020 that it would, forthwith, take all possible steps to avoid similar breaches of the Code occurring in the future. In addition, Daiichi-Sankyo was reported to the Code of Practice Appeal Board for it to decide whether the imposition of further sanctions was appropriate.

Turning to the current case, the Panel noted Daiichi-Sankyo's submission that transfers of value of £857,000 to healthcare organisations in 2017, 2018 and 2019 in relation to therapy reviews were missing from its Disclosure UK submission in 2018, 2019 and 2020, respectively.

The Panel noted that two codes applied to the time period at issue. The 2019 Code and the 2016 Code. However, the clauses at issue were the same in each Code; the only difference related to the supplementary information to Clause 24.1, Consent to Disclosure. As this change to the supplementary information was not relevant to this case, the Panel decided therefore to consider the case under the 2019 Code.

The Panel noted that Clause 24.2 described the transfers of value covered by Clause 24.1 and included, *inter alia*, donations, grants and benefits-in-kind provided to institutions, organisations and associations in accordance with Clauses 19.1 and 19.2. Failure to document and publicly disclose transfers of value as described in Clause 24.2 would be a breach of Clause 24.1.

The Panel considered that, the information published on Disclosure UK when this voluntary admission was submitted in August 2020, was not comprehensive in relation to 2017 and 2018 transfers of value provided to healthcare organisations for therapy reviews. The Panel ruled a breach of Clause 24.1 for each of those years. Consequently, as the data had not been disclosed, Daiichi-Sankyo had not met the requirement to disclose by 30 June of the relevant year and the Panel ruled a breach of Clause 24.4 for each of those years.

The Panel noted that during the Covid-19 pandemic in 2020, the ABPI and the PMCPA agreed that it would not be appropriate to write to NHS workers, hospitals and other NHS organisations at that time as it would add additional load while the NHS was rightly focussed on responding to the pandemic. To prevent the annual communications from being distributed, on 30 June 2020 companies' 2019 non-R&D data was temporarily published on Disclosure UK in aggregate, instead of being broken down by individuals and organisations. The Panel noted that companies were, however, encouraged to publish the detailed 2019 data on their own websites where able to lawfully and operationally. The 2019 disclosure data was re-published on 27 November 2020 disaggregated, as normal on Disclosure UK.

The Panel noted that the temporary change to disclosure as a result of the pandemic should not have affected the disclosure of Daiichi-Sankyo's 2019 transfers of value to healthcare organisations in relation to therapy reviews in aggregate by 30 June 2020. The Panel noted, however, that Daiichi-Sankyo had not submitted the relevant data to Disclosure UK. The Panel

therefore considered, that the information published on Disclosure UK when this voluntary admission was submitted in August 2020, was not comprehensive in relation to 2019 transfers of value provided to healthcare organisations for therapy reviews. The Panel ruled a breach of Clause 24.1 in relation to the omitted 2019 data as acknowledged by Daiichi-Sankyo. Consequently, as the data had not been disclosed, Daiichi-Sankyo had not met the requirement to disclose the data, albeit in aggregate in the temporary circumstances described above, by 30 June 2020 and the Panel therefore ruled a breach of Clause 24.4.

The Panel considered that the magnitude of under-reporting was of serious concern and queried why the issue had not come to light sooner particularly given Case AUTH/3285/12/19 and that the company's undertaking in that case was provided on 13 February 2020.

The Panel noted Daiichi-Sankyo's original submission that it had collated the data relevant to the transfers of value associated with therapy reviews. Daiichi-Sankyo subsequently submitted that the root cause explanation for the reporting oversight was that its processes failed to identify that the therapy reviews were within the scope of disclosure.

The Panel noted Daiichi-Sankyo's further submission that it had spent the past few weeks with three service providers to reconcile and collate the healthcare organisation-level details for the therapy review invoices in its system and £35,000 in relation to transfers of value in 2017 could not be fully identified. The Panel, therefore, queried whether the company's original submission that it had collated the data to begin with was thus completely accurate.

The Panel was concerned to note Daiichi-Sankyo's submission that whilst it had reconciled and collated the healthcare organisation-level details for the therapy review invoices in its system for £822,000 (96%) of the total amount, which included £65,000 in 2017, £259,000 in 2018 and £498,000 in 2019, there was still £35,000 (4%) that could not be fully identified as a service provider no longer had records for the 2017 period.

The Panel was further concerned to note that the error had only come to light after the company's 2019 transfers of value submissions to Disclosure UK and was only identified as a result of an audit that Daiichi-Sankyo had commissioned to assess the robustness of its Code-related governance framework. The disclosure of transfers of value was an important part of self-regulation and it was of serious concern that Daiichi-Sankyo had significantly under-reported transfers of value to healthcare organisations in relation to therapy reviews for so many years. High standards had not been maintained and therefore the Panel ruled a breach of Clause 9.1 as acknowledged by Daiichi-Sankyo.

The Panel noted that a ruling of a breach of Clause 2 was used as a sign of particular censure. It considered that the failure to disclose the required information on Disclosure UK was extremely concerning as was the scale of the under-reporting. Daiichi-Sankyo's processes were wholly inadequate in that regard. The Panel ruled a breach of Clause 2.

The Panel noted that a form of undertaking and assurance was an important document which underpinned self-regulation. Companies had to give an undertaking that all possible steps would be taken to avoid similar breaches of the Code in future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that Daiichi-Sankyo had provided its signed undertaking in relation to Case AUTH/3285/12/19 on 13 February 2020. In the Panel's view, whilst the failure to disclose the 2017 and 2018 transfers of value to healthcare organisations in relation to therapy reviews by 30 June 2018 and 30 June 2019, respectively, were not covered by that undertaking, the Panel noted that when this voluntary admission was submitted in August 2020, the relevant data for 2017 and 2018 had still not been disclosed. Furthermore, the Panel noted that 2019 transfer of values to healthcare organisations in relation to therapy reviews had not been disclosed, albeit in aggregate in the temporary circumstances due to the Covid-19 pandemic, by 30 June 2020. Furthermore, it appeared that the company's processes in relation to disclosing transfers of value as required by the Code remained inadequate. In the Panel's view, Daiichi-Sankyo had breached its undertaking given in Case AUTH/3285/12/19 and a breach of Clause 29 was ruled.

The Panel considered that Daiichi-Sankyo's failure to comply with its undertaking given in Case AUTH/3285/12/19 meant that it had not maintained high standards and had brought discredit upon, and reduced confidence in, the industry. A breach of Clauses 9.1 and 2, a sign of particular censure, were ruled.

The Panel was extremely concerned that a breach of undertaking occurred, despite the Code of Practice Appeal Board publicly reprimanding Daiichi-Sankyo for its fundamental systemic failure to have adequate processes in place to correctly disclose transfers of value and requiring the company to be audited in relation to Case AUTH/3285/12/19. The Panel noted that the under-reported figure in the current case (Case AUTH/3375/8/20) (£857,000) was almost double that estimated to have been under-reported in Case AUTH/3285/12/19 (£471,000). The Panel also noted that at the date that it considered this case the Code of Practice Appeal Board in Case AUTH/3285/12/19 had previously decided that Daiichi-Sankyo should be the subject of a re-audit. The Panel, however, considered that, on balance, and bearing in mind the need for proportionate regulation, it would not report Daiichi-Sankyo to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for this current case as closely similar matters had been at issue in Case AUTH/3285/12/19 which had led to the ongoing audit process and the forthcoming re-audit would refer to Case AUTH/3375/8/20. The Panel further bore in mind that the Appeal Board received all cases completed at the Panel level and therefore the Appeal Board could, at that point, consider if additional sanctions might be appropriate in relation to Case AUTH/3375/8/20.

Complaint received **28 August 2020**

Case completed **12 February 2021**